K101592

APPENDIX A: 510(k) SUMMARY

OCT - 6 2011

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

A. Name, Address, Phone and Fax number of the Applicant

Cheng Medical Corporation.
12945 Saratoga Avenue
Saratoga, CA 95070
Telephone: (408) 255-3223
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B. Contact Person

Mary P. Gallup
Regulatory Affairs Consultant
Hantel Technologies, Inc.
Telephone: (510) 441-4017

C. Date Prepared

06/04/2010

D. Device Name

Trade Name:
Model **HC-0001** Erase Pen
Model **CS-0001** Erase Tip
Regulation Number: 21 CFR 882.4400 and 21 CFR 882.4725
Regulation Number: Radiofrequency Lesion Generator and Lesion Probe
Regulation Class: II
Product Code: GXD, GXI

E. Device Description

The Erase Pen (hand-held Bi-Polar Radiofrequency battery operated controller) and the Erase Tip (single use, sterile detachable electrode cartridge system) is a hand-held Electrosurgical Device to locate and ablate nerves. The depth of the electrodes, the amount of RF energy delivered, and the duration of energy applied control the size of the ablation.

F. Intended Use

The Erase Pen and Erase Tip (Single use Sterile Detachable Electrode Cartridge system) is intended to create radiofrequency (RF) heat lesion in nerve tissue. It is intended for use only by trained clinicians in hospital or clinical setting.

G. Substantial Equivalence

The Erase Pen Model **HC-0001** and Erase Tip Model **CS-0001** is substantially equivalent in the following technological ways to the identified predicate device: Radionic's RFG-3C (K982489) system.

- Indication For Use
- RF Energy Type – Bi Polar
- Functional (stimulation and ablation)
- Probe Type (single use)

Erase Pen Operating Characteristics compared with predicate device

Parameter	Erase Pen	Radionics RFG-3C
a. Maximum voltage deliverable, Vp-p	56 into 2000Ω and 3000Ω load	200 into 2000Ω load*
b. Maximum current deliverable, amps	0.18 into 100Ω load	0.70 into 100Ω load
c. Maximum power deliverable, watts	3.5 into 100Ω load	50 into 100Ω load
d. Maximum voltage accessible, Vp-p	71	161
e. Maximum current accessible, amps	0.20	1.17
f. Maximum power accessible, watts	5	68
g. Frequency of RF energy, kHz	460+/-5%	500+/-10%
h. Shape of the waveform during RF ablation	sinusoidal	sinusoidal
i. Shape of the waveform during Tissue Stimulation	200μs one-shot pulse (monophasic square wave)	200μs one-shot pulse (monophasic square wave)
j. Impedance cutoffs, ohms	20 to 220	50 to 5000
k. Maximum current limit, amps	0.18	0.70

Note: The set output level Erase Pen and adjustable output level Radionics RF generators would have an output power equivalence when the Radionics RFG-3C is at a setting of 3 to 5, depending on the tissue impedance.

* Information not available for the maximum voltage deliverable of the Radionics RFG-3C into a 3000Ω impedance.

H. Device Testing Results and Conclusion

All necessary testing was performed on the Erase Pen Model HC-0001 and Erase Tip (Single use Sterile Detachable Electrode Cartridge system) Model CS-0001 to ensure that the product is substantially equivalent to the predicate devices and to ensure that the new device does not raise new issues regarding safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Cheng Medical Corporation
c/o Mary Pascual Gallup
Vice President of Regulatory Affairs, Consultant
Hantel Technologies, Inc.
12945 Saratoga Avenue
Saratoga, California 95070

OCT - 6 2011

Re: K101592
Trade/Device Name: Erase Hand-held Controller and Erase Single Use Electrode Cartridge System
Regulation Number: 21 CFR 882.4400
Regulation Name: Radiofrequency lesion generator
Regulatory Class: Class II
Product Code: GXD
Dated: September 28, 2011
Received: September 30, 2011

Dear Ms. Pascual Gallup:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4: INDICATION FOR USE STATEMENT

Indications for Use

510(k) Number (if known): K101592

Device Name:

Model **HC-0001** The Erase Pen

Model **CS-0001** The Erase Tip

Indications for Use:

The Erase Pen (RF Controller) is only used with the Erase Tip (Single Use Sterile Detachable Electrode Cartridge system) for thermal coagulation of soft tissue and peripheral nerves by creating radiofrequency (RF) lesions in nerve tissue. It is intended for use only by trained clinicians in hospital or clinical setting.

Prescription Use _Yes_ and/or Over-The-Counter Use _No_

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

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